EUROPEAN
COMMISSION

Brussels, 22.2.2022
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COMMISSION DELEGATED REGULATION (EU) …/...

of 22.2.2022

amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the issuance of certificates of recovery based on rapid antigen tests

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2021/953[1] establishes a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic.

According to Regulation (EU) 2021/953, a certificate of recovery confirms that, following a positive result of a molecular nucleic acid amplification test (NAAT) carried out by health professionals or by skilled testing personnel, the holder has recovered from a SARS-CoV-2 infection. Certificates of recovery can thus currently not be issued based on other types of tests, such as rapid antigen tests.

In May 2021, the Health Security Committee, established by Article 17 of Decision No 1082/2013/EU[2], set up a technical working group on COVID-19 diagnostic tests[3]. This technical working group brings together experts from the Member States and Norway as well as representatives from the Directorate-General for Health and Food Safety, the Joint Research Centre and the European Centre for Disease Prevention and Control (ECDC).

The aim of this technical working group is to review proposals put forward by Member States and manufacturers for COVID-19 rapid antigen tests to be included in the EU common list of rapid antigen tests agreed by the Health Security Committee[4]. In accordance with Article 3(1)(b) of Regulation (EU) 2021/953, only COVID-19 rapid antigen tests included in that list can form the basis for the issuance of a test certificate in the EU Digital COVID Certificate format. The technical working group assesses these proposals against the criteria established by the Council Recommendation of 21 January 2021[5] as well as further criteria that the group agreed upon on 21 September 2021[6]. One of the criteria agreed upon was an increased specificity rate of over 98%.

The EU common list includes CE-marked rapid antigen tests that are in use and have been validated in at least one Member State, and the clinical performance of which was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens. In July 2021, the technical working group agreed to exclude from the list rapid antigen tests that are solely based on other sampling materials, such as saliva, sputum, blood and/or faeces. Furthermore, the list neither includes pooled rapid antigen tests nor rapid antigen self-tests. The list only includes rapid antigen tests conducted by trained healthcare personnel or, where appropriate, trained operators, further increasing the likely consistency of the performance of the tests included in the list.

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1 Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 1).

2 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

3 https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en

4 https://ec.europa.eu/health/system/files/2022-01/covid-19_rat_common-list_en.pdf

5 Council Recommendation of 21 January 2021 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (OJ C 24, 22.1.2021, p. 1).

6 More details available in the EU common list: https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en

If the experts of the technical working group deem it necessary to update the EU common list, a proposal is submitted to the Health Security Committee for agreement. The technical working group has thus put in place a structured, coherent and swift procedure for assessing the clinical performance of rapid antigen tests that have been validated through independent evaluation studies, resulting in an update of the EU common list at least once a month.

On 11 January 2022, the technical working group on COVID-19 diagnostic tests discussed the use of rapid antigen tests for certificates of recovery, taking into account the worsened epidemiological situation, with record high numbers of COVID-19 cases due to the 'Omicron' variant of concern, as well as shortages of NAAT capacities in various Member States as a result of a high testing demand. Given these circumstances, the technical working group agreed that rapid antigen tests included in the EU common list could be used to issue certificates of recovery. The technical work group stressed that only the results of rapid antigen tests conducted by medical professionals or other trained personnel should be used to issue such certificates.

The European Centre for Disease Prevention and Control (ECDC) considers that appropriately validated rapid antigen tests that meet high specificity criteria of more than 98% could be used to certify that a person has recovered from a past SARS-CoV-2 infection[7]. The higher the specificity, the higher the test validity to be used for certifying a recovered individual.

In view of the above, and based on further consultations with the Health Security Committee, the Commission considers that it is appropriate to amend Regulation (EU) 2021/953 to provide that certificates of recovery can also be issued following a positive result of a rapid antigen test listed in the EU common list and carried out by health professionals or by skilled testing personnel by the Member State where the test was carried out.

In this context, it is necessary to take into account that COVID-19 testing strategies differ between Member States, and that not all Member States are experiencing a shortage of NAAT capacities. The issuance of certificates of recovery following a positive result of a rapid antigen test should thus remain optional. In particular, where sufficient NAAT capacity is available, Member States could continue to issue certificates of recovery only on the basis of NAATs, which are considered as the most reliable methodology for the testing of COVID-19 cases and contacts. Similarly, Member States could issue certificates of recovery based on rapid antigen tests during periods of increased SARS-CoV-2 infections and a resulting high testing demand or shortage of NAAT capacity, and could return to issuing certificates of recovery only based on NAATs once infections decrease. At the same time, it is important that citizens can obtain certificates of recovery when having tested positive for SARS-CoV-2.

The validity of a certificate of recovery should start at the earliest 11 days after the date on which the person was first subject to a NAAT or rapid antigen test that produced a positive result. According to ECDC[8], evidence shows that the probability of transmission in the days after symptom onset decreases gradually from day three until day ten, and that individuals with mild or moderate disease are unlikely to be infectious beyond 10 days of symptoms[9].

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7 https://www.ecdc.europa.eu/sites/default/files/documents/Options-for-the-use-of-rapid-antigen-tests-for-COVID-19-first-update.pdf

8 https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19-third-update.pdf

9 Among hospitalised and/or severe COVID-19 patients, isolation of SARS-CoV-2 virus is possible until day 20 after onset of symptoms, however, such patients are very unlikely to travel in a non-medical setting.

In accordance with Article 7(8) of Regulation (EU) 2021/953, where Member States accept proof of recovery from SARS-CoV-2 infection in order to waive restrictions to free movement put in place, in accordance with Union law, in response to the COVID-19 pandemic, they are required to accept, under the same conditions, certificates of recovery issued by other Member States. Following the adoption of this delegated regulation, Article 7(8) of Regulation (EU) 2021/953 will also cover certificates of recovery issued following a positive result of a rapid antigen test listed in the EU common list, even if the Member State concerned does not itself issue certificates of recovery based on such tests.

To facilitate free movement, notably of citizens who have been infected during the Omicron wave, Member States should be able to issue certificates of recovery retroactively, that is, based on tests carried out as from 1 October 2021, provided that the rapid antigen test used was included in the EU common list at the time the test result was produced. As of 1 October 2021, all rapid antigen tests included in the EU common list have been assessed against the further definitions, scope, considerations and criteria that had been agreed by the Health Security Committee on 21 September 2021. Moreover, this also covers the period when the emergence of Omicron led to a substantial increase in SARS-CoV-2 infections in the EU, resulting in a very high testing demand and strained NAAT capacities. Retroactive issuance could take place on the basis of either data recorded in Member States' healthcare records or a test certificate issued in the EU Digital COVID Certificate format.

As noted by ECDC as well as the technical working group on COVID-19 diagnostic tests, the predictive value of rapid antigen test is highest in settings where SARS-CoV-2 prevalence, that is, the number of cases at a certain point of time, is high, and false positives may occur when the prevalence is low. While, as a result of the emergence of Omicron, the virus is currently circulating at very high levels, circulation may decrease over the coming months, in particular during the summer. The Commission, supported by ECDC, the Health Security Committee and its technical working group on COVID-19 diagnostic tests, will monitor these developments closely. Finally, the Commission will also monitor whether newly emerging scientific evidence warrants a change to the validity period of certificates of recovery.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Before adopting this delegated act, the Commission consulted the EU Digital COVID Certificate Expert Group on 10 and 17 February 2022. During the meeting of 10 February 2022, the EU Digital COVID Certificate Expert Group discussed various policy options regarding the issues covered by this delegated regulation and expressed support for its swift entry into force. During the meeting of 17 February 2022, the group had an exchange of views on a draft version of this delegated regulation.

The European Parliament and the Council were informed of the meetings of the EU Digital COVID Certificate Expert Group where a draft version of this delegated regulation was discussed and both institutions, therefore, received all relevant documents at the same time as Member States' experts in line with the 2016 Interinstitutional Agreement on Better Law Making and the Common understanding on Delegated Acts annexed to it.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 7(4) of Regulation (EU) 2021/953 empowers the Commission to adopt, on the basis of guidance received pursuant to Article 3(11) of that Regulation, delegated acts to amend Articles 3(1)(c) and 7(1) of that Regulation to allow for the issuance of the certificate of recovery on the basis of a positive rapid antigen test, antibody test, including a serological test for antibodies against SARS-CoV-2, or any other scientifically validated method. Such

delegated acts are also to amend point 3 of the Annex to Regulation (EU) 2021/953 by adding, modifying or removing the data fields falling under the categories of personal data referred to in Article 7(2)(b) and (c) of Regulation (EU) 2021/953.

As mentioned above, guidance received both from ECDC and the Health Security Committee support the issuance of certificates of recovery based on CE-marked rapid antigen tests listed in the EU common list and carried out by health professionals or by skilled testing personnel.

Pursuant to Article 7(7) of Regulation (EU) 2021/953, where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the urgency procedure provided for in Article 13 of the Regulation is to apply to delegated acts adopted pursuant to Article 7 of that Regulation.

To ensure that, in light of newly emerging scientific evidence as to the reliability of rapid antigen tests, Union citizens can, when exercising free movement, profit from the possibility to use certificates of recovery issued based on rapid antigen tests as quickly as possible, imperative grounds of urgency require the use of the procedure provided for in Article 13 of Regulation (EU) 2021/953. Delaying immediate action would also aggravate the risk of citizens being unable to receive certificates of recovery due to the shortage of NAATs as a result of the Omicron wave.

Article 1 contains the amendments to Regulation (EU) 2021/953, which are:

– A reference to rapid antigen tests listed in the EU common list of COVID-19 rapid antigen tests agreed by the Health Security Committee is added to the definition of certificates of recovery in Article 3(1)(c).

– An addition to Article 7(1) according to which Member States may issue certificate of recovery also following a positive result of a rapid antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee carried out by health professionals or by skilled testing personnel. The possibility to issue certificates of recovery should apply retroactively, that is, based on tests carried out as from 1 October 2021. Member States should be able to do so provided that the rapid antigen test carried out was included in the EU common list of COVID-19 antigen tests at the time the test result was produced.

– The removal of the explicit references to NAATs from the data fields set out in point 3 of the Annex, which concern the personal data to be included in certificates of recovery, to ensure that the data fields can also include data on the positive result of a rapid antigen test.

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amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the issuance of certificates of recovery based on rapid antigen tests

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2021/953 of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic[1], and in particular Article 7(4) and (7) thereof,

Whereas:

(1) Regulation (EU) 2021/953 lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. It also contributes to facilitating the gradual lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

(2) According to point (c) of Article 3(1) of Regulation (EU) 2021/953, the EU Digital COVID Certificate framework allows for the issuance, cross-border verification and acceptance of a certificate confirming that, following a positive result of a nucleic acid amplification test (NAAT) carried out by health professionals or by skilled testing personnel, the holder has recovered from a SARS-CoV-2 infection (certificate of recovery).

(3) In May 2021, the Health Security Committee established by Article 17 of Decision No 1082/2013/EU[2] set up a technical working group on COVID-19 diagnostic tests[3], which brings together experts from the Member States and Norway as well as representatives from the Commission and the European Centre for Disease Prevention and Control ('ECDC').

(4) The aim of that technical working group is to review the proposals put forward by Member States and manufacturers for COVID-19 rapid antigen tests to be included in the EU common list of rapid antigen tests agreed by the Health Security Committee[4]. In accordance with Article 3(1), point (b), of Regulation (EU) 2021/953, only COVID-

[1] OJ L 211, 15.6.2021, p. 1.

[2] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

[3] https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en

[4] https://ec.europa.eu/health/system/files/2022-01/covid-19_rat_common-list_en.pdf

19 rapid antigen tests included in that list can form the basis for the issuance of a test certificate in the EU Digital COVID Certificate format. The technical working group assesses these proposals against the criteria established by the Council Recommendation of 21 January 2021[5] as well as further criteria that the group agreed upon on 21 September 2021. One of the criteria agreed upon was an increased specificity rate of over 98%.

(5) The EU common list includes CE-marked rapid antigen tests that are in use and have been validated in at least one Member State, and the clinical performance of which was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens. In July 2021, the technical working group agreed to exclude from the list rapid antigen tests that are solely based on other sampling materials, such as saliva, sputum, blood or faeces. Furthermore, the list of antigen tests neither includes pooled rapid antigen tests nor rapid antigen self-tests. The list only includes rapid antigen tests conducted by trained healthcare personnel or, where appropriate, trained operators, further increasing the likely consistency of the performance of the tests included in the list.

(6) If the technical working group deems it necessary to update the EU common list, a proposal is submitted to the Health Security Committee for agreement. The technical working group has thus put in place a structured, coherent and swift procedure for assessing the clinical performance of rapid antigen tests that have been validated through independent evaluation studies, resulting in an update of the EU common list at least once a month.

(7) On 11 January 2022, the technical working group on COVID-19 diagnostic tests discussed the use of rapid antigen tests for certificates of recovery, taking into consideration the worsened epidemiological situation, with record high numbers of COVID-19 due to the 'Omicron' variant of concern, as well as shortages of NAAT capacities in various Member States as a result of a high testing demand. Given these circumstances, the technical working group agreed that rapid antigen tests included in the EU common list could be used to issue certificates of recovery. The technical working group stressed that only the results of rapid antigen tests conducted by medical professionals or other trained personnel should be used to issue such certificates.

(8) ECDC considers that appropriately validated rapid antigen tests that meet high specificity criteria of more than 98% could be used to certify that a person has recovered from a past SARS-CoV-2 infection[6]. The higher the specificity, the higher the test validity to be used for certifying a recovered individual.

(9) As a result, and based on further consultations with the Health Security Committee, it is appropriate to amend Regulation (EU) 2021/953 to provide that certificates of recovery can also be issued following a positive result of a rapid antigen test listed in the EU common list and carried out by health professionals or by skilled testing personnel by the Member State where the test was carried out. The rapid antigen test used should be included in the EU common list at the time the test result was

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5 Council Recommendation of 21 January 2021 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (OJ C 24, 22.1.2021, p. 1).

6 https://www.ecdc.europa.eu/sites/default/files/documents/Options-for-the-use-of-rapid-antigen-tests-for-COVID-19-first-update.pdf

produced, and its possible subsequent removal from the EU common list should not affect the validity of certificates of recovery already issued.

(10) In this context, it is necessary to take into account that COVID-19 testing strategies differ between Member States, and that not all Member States are experiencing a shortage of NAAT capacities. The issuance of certificates of recovery following a positive result of a rapid antigen test should thus remain optional. In particular, where sufficient NAAT capacity is available, Member States could continue to issue certificates of recovery only on the basis of NAAT tests, which are considered as the most reliable methodology for the testing of COVID-19 cases and contacts. Similarly, Member States could issue certificates of recovery based on rapid antigen tests during periods of increased SARS-CoV-2 infections and a resulting high testing demand or shortage of NAAT capacity, and could return to issuing certificates of recovery only based on NAAT tests once infections decrease. At the same time, it is important that citizens can obtain certificates of recovery when having tested positive for SARS-CoV-2.

(11) In accordance with Article 7(8) of Regulation (EU) 2021/953, where Member States accept proof of recovery from SARS-CoV-2 infection in order to waive restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2, they are required to accept, under the same conditions, certificates of recovery issued by other Member States. Following the adoption of this Regulation, Article 7(8) of Regulation (EU) 2021/953 therefore also covers certificates of recovery issued following a positive result of a rapid antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, carried out by health professionals or by skilled testing personnel, even if the Member State concerned does not itself issue certificates of recovery based on such tests.

(12) Regulation (EU) 2021/953 should therefore be amended accordingly.

(13) To facilitate free movement, in particular of citizens who have been infected during the Omicron wave, Member States should be able to issue certificates of recovery retroactively, that is, based on rapid antigen tests carried out as from 1 October 2021, provided that the rapid antigen test concerned was included in the EU common list at the time the test result was produced. As of 1 October 2021, all rapid antigen tests included in the EU common list have been assessed against the further definitions, scope, considerations and criteria that had been agreed by the Health Security Committee on 21 September 2021. Moreover, such retroactive issuance also covers the period when the emergence of Omicron led to an increase in SARS-CoV-2 infections in the EU, resulting in a high testing demand and strained NAAT capacities. Retroactive issuance could take place on the basis of either data recorded in Member States' healthcare records or a test certificate issued in the EU Digital COVID Certificate format.

(14) In accordance with Articles 3(10) and 8(2) of Regulation (EU) 2021/953, certificates of recovery covered by an implementing act adopted pursuant to those provisions are to be accepted under the same conditions as EU Digital COVID Certificates. Accordingly, such certificates should be accepted if they have been issued following a positive result of a NAAT test, or a rapid antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, both of which should be carried out by health professionals or by skilled testing personnel.

(15) Pursuant to Article 7(7) of Regulation (EU) 2021/953, where, in the case of newly emerging scientific evidence, imperative grounds of urgency so require, the urgency

procedure provided for in Article 13 of that Regulation is to apply to delegated acts adopted pursuant to Article 7(4).

(16) As noted by ECDC as well as the technical working group on COVID-19 diagnostic tests, the predictive value of rapid antigen test is highest in settings where SARS-CoV-2 prevalence, that is, the number of cases at a certain point of time, is high, and false positives may occur when the prevalence is low. While, as a result of the emergence of Omicron, the virus is currently circulating at very high levels, circulation may decrease over the coming months. It is thus necessary for the Commission, supported by ECDC, the Health Security Committee and its technical working group on COVID-19 diagnostic tests, to monitor these developments closely.

(17) To ensure that, in light of newly emerging scientific evidence as to the reliability of rapid antigen tests, Union citizens can, when exercising free movement, profit from the possibility to use certificates of recovery issued based on rapid antigen tests as quickly as possible, imperative grounds of urgency require the use of the procedure provided for in Article 13 of Regulation (EU) 2021/953. Delaying immediate action would also aggravate the risk of citizens being unable to receive certificates of recovery due to the shortage of NAAT as a result of the Omicron wave.

(18) Given the urgency of the situation related to the COVID-19 pandemic, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2021/953 is amended as follows:

(1) in Article 3(1), point (c) is replaced by the following:

"(c) a certificate confirming that, following a positive result of a NAAT test, or a rapid antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, carried out by health professionals or by skilled testing personnel, the holder has recovered from a SARS-CoV-2 infection (certificate of recovery).";

(2) in Article 7, paragraph 1 is replaced by the following:

"1. Each Member State shall issue, upon request, certificates of recovery referred to in point (c) of Article 3(1) following a positive result of a NAAT test carried out by health professionals or by skilled testing personnel.

A Member State may also issue, upon request, certificates of recovery referred to in point (c) of Article 3(1) following a positive result of a rapid antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee carried out by health professionals or by skilled testing personnel.

Member States may issue certificates of recovery based on rapid antigen tests carried out by health professionals or by skilled testing personnel on or after 1 October 2021, provided that the rapid antigen test used was included in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee at the time the positive test result was produced.

Certificates of recovery shall be issued at the earliest 11 days after the date on which a person was first subject to a NAAT test or rapid antigen test that produced a positive result.

The Commission is empowered to adopt delegated acts in accordance with Article 12 to amend the number of days after which a certificate of recovery is to be issued, on the basis of guidance received from the Health Security Committee in accordance with Article 3(11) or on scientific evidence reviewed by ECDC.";

(3) the Annex to Regulation (EU) 2021/953 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22.2.2022

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, 22.2.2022
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ANNEX

ANNEX

to the

COMMISSION DELEGATED REGULATION (EU) .../...

amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the issuance of certificates of recovery based on rapid antigen tests

ANNEX

The Annex to Regulation (EU) 2021/953 is amended as follows:

(1) Point 3 of the Annex to Regulation (EU) 2021/953 is replaced by the following:

"3. Data fields to be included in the certificate of recovery:

(a) name: surname(s) and forename(s), in that order;

(b) date of birth;

(c) disease or agent from which the holder has recovered: COVID-19 (SARS-CoV-2 or one of its variants);

(d) date of first positive test result;

(e) Member State or third country in which test was carried out;

(f) certificate issuer;

(g) certificate valid from;

(h) certificate valid until (not more than 180 days after the date of first positive test result);

(i) unique certificate identifier.".